SEP 1 1 2000

510(K) SUMMARY

K002739

Submitted by:

Vicki Drews
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Proposed Device:

Infusor Patient Control Module, 2 mL

Predicate Device:

Infusor Patient Control Module (0.5 mL reservoir), cleared under K853881, cleared December 2, 1985.

Device Description and Statement of Intended Use:

The PCM is intended for use as an accessory to Baxter Infusors. It is a single-use, disposable device which allows for intermittent bolus doses of medication on patient demand.

The 2 mL PCM is designed to be worn on the patient's clothing or belt. When the PCM Medication Demand Button is depressed, a small quantity of drug solution is delivered. Depression of the button empties the PCM reservoir. Upon release of the button, the PCM reservoir begins to refill with medication. The time required to fill the PCM reservoir is determined by the flow rate of the Baxter Infusor used with the PCM.

Summary of Technological Characteristics of New Device to Predicate Device

The technological characteristics of the 2 mL Patient Control Module do not differ significantly from the currently marketed 0.5 mL Patient Control Module. The devices utilize the same materials and fundamental scientific technology and have the same intended use.

Discussion of Non-Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2000

Ms. Vicki Drews
Manager of Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K002739
Trade Name: Infusor Patient Control Module, 2mL, Model 2C1067K
Regulatory Class: II
Product Code: MEA
Dated: August 31, 2000
Received: September 1, 2000

Dear Ms. Drews:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Trade Name: Infusor Patient Control Module, 2 mL

Indication for Use: The 2 mL Patient Control Module is intended for use as an accessory to Baxter Infusors. It allows for intermittent bolus doses of medication on patient demand.

Patricia Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K002739